reduce the opiate alkaloid content of poppy seeds. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments. We intend to use the information to help determine what type(s) of actions, if any, we should take to help ensure that poppy seed products do not pose a health risk when consumed.

DATES: FDA is extending the comment period on the notice published January 15, 2025 (90 FR 3873). Either electronic or written comments on the notice must be submitted by June 16, 2025.

ADDRESSES: You may submit comments and information as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 9, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–P–0168 for ''Growing, Harvesting, Processing, and Distribution of Poppy Seeds—Industry Practices Related to Opiate Alkaloids; Request for Information.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Jesse Lunzer, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2879.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 15, 2025 (90 FR 3873), we published a notice requesting information on industry practices related to poppy seeds, such as information about growing, harvesting, processing, and distribution of poppy seeds, including industry practices to reduce the opiate alkaloid content of poppy seeds. We intend to use the information to help determine what type(s) of actions, if any, we should take to help ensure that poppy seed products do not pose a health risk when consumed. We provided a 90-day comment period for the request for information.

We have received requests for a 90-day extension of the comment period. In general, the requests explained that industry needed more time to collect, review, and summarize the information requested for the global supply chain.

We have considered the requests and are extending the comment period for an additional 60 days. We believe that this extension will allow adequate time for interested persons to submit comments.

Dated: March 28, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–06049 Filed 4–8–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5925]

21st Century Cures Act: Annual Compilation of Notices of Updates From the Susceptibility Test Interpretive Criteria Web Page; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of the Agency's annual compilation of notices of updates to the Agency's Susceptibility Test Interpretive Criteria web page. The Agency established the Susceptibility Test Interpretive Criteria web page on December 13, 2017, and

since establishment has provided updates to both the format of the web pages and the susceptibility test interpretive criteria identified and recognized by FDA on the web pages. FDA is publishing this notice in accordance with procedures established by the 21st Century Cures Act (Cures Act).

DATES: This notice is published in the **Federal Register** on April 9, 2025.

ADDRESSES: You may submit either electronic or written comments and information as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed below (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–5925 for ''Susceptibility Test Interpretive Criteria Recognized and Listed on the Susceptibility Test Interpretive web page; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Deborah Kim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6349, Silver Spring, MD 20993–0002, 301–796–9053, *Deborah.Wang@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 511A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360a–2), as added by section 3044 of the Cures Act (Pub. L. 114–255), was signed into law on December 13, 2016. This provision clarified FDA's authority to identify and efficiently update susceptibility test interpretive criteria, including through the recognition by FDA of standards established by standards development organizations (SDOs). It also clarified that sponsors of antimicrobial susceptibility testing devices may rely on listed susceptibility test interpretive criteria to support premarket authorization of their devices, provided they meet certain conditions, which allows for a more streamlined process for incorporating up-to-date information into such devices.

In the **Federal Register** notice of December 13, 2017 (82 FR 58617), FDA announced the establishment of the Susceptibility Test Interpretive Criteria web page. This web page recognizes susceptibility test interpretive criteria established by an SDO that fulfills the requirements under section 511A(b)(2)(A) of the FD&C Act; identifies when FDA does not recognize, in whole or in part, susceptibility test interpretive criteria established by an SDO; and lists susceptibility test interpretive criteria identified by FDA outside the SDO process. The susceptibility test interpretive criteria listed by FDA on the Susceptibility Test Interpretive Criteria web page is deemed to be recognized as a standard under section 514(c)(1) of the FD&C Act (21 U.S.C. 360d(c)(1)). The Susceptibility Test Interpretive Criteria web page can be found at *https://www.fda.gov/STIC*.

On March 1, 2018, FDA published a notice in the **Federal Register** (83 FR 8883) requesting comments on FDA's initial susceptibility test interpretive criteria recognition and listing determinations on the Susceptibility Test Interpretive Criteria web page (*https://www.federalregister.gov/documents/2018/03/01/2018-04175/susceptibility-test-interpretive-criteria-recognized-and-listed-on-the-susceptibility-test*). FDA may consider information provided by interested third parties as a basis for evaluating new or updated interpretive criteria standards (section 511A(c)(2)(B) of the FD&C Act); third parties should submit any information they wish to convey to the Agency to Docket No. FDA–2017–N–5925. If comments are received, FDA will review those comments and will make, as appropriate, updates to the recognized standards or susceptibility test interpretive criteria.

At least every 6 months after the establishment of the Susceptibility Test Interpretive Criteria web page, FDA is

required, as appropriate to: (1) publish on that web page a notice recognizing new or updated susceptibility test interpretive criteria standards, or recognizing or declining to recognize parts of standards; (2) withdraw recognition of susceptibility test interpretive criteria standards, or parts of standards; and (3) make any other necessary updates to the lists published on the Susceptibility Test Interpretive Criteria web page (section 511A(c)(1)(A) of the FD&C Act). FDA has provided notices of updates on the Susceptibility Test Interpretive Criteria web page, which can be found here: *https://www.fda.gov/drugs/development-resources/notice-updates*. Interested parties may also sign up to receive emails informing them of these updates as they occur by using the link provided either on the main Susceptibility Test Interpretive Criteria web page (*https://www.fda.gov/STIC*) or on the updates page.

Once a year, FDA is required to compile the new notices published on the Susceptibility Test Interpretive Criteria web page, publish them in the **Federal Register**, and provide for public comment (see section 511A(c)(3) of the FD&C Act). This **Federal Register** notice satisfies that requirement. If comments are received, FDA will review them and make updates to the recognized standards or susceptibility test interpretive criteria as needed.

II. Annual Compilation of Notices, 2024: Susceptibility Test Interpretive Criteria Web Page

A. Updates to Standards Recognition

As of May 28, 2024, the following standards are no longer recognized: ''Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Susceptibility Testing, 33rd ed. CLSI supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2023.''

As of May 28, 2024, with certain exceptions, FDA recognizes the standard published in: ''Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Susceptibility Testing, 34th ed. CLSI supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2024.''

B. Updates by Drug

TABLE 1—NOTICES OF UPDATES TO RECOGNIZED OR UPDATED SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA (STIC) BY DRUG [1]

Drug	Route of administration	Action taken	Therapeutic category	Date
Cefepime and Enmetazobactam	Injection	FDA identified STIC (MIC and disk diffusion) for Enterobacterales and *Pseudomonas aeruginosa*.	Antibacterial	2/22/2024
Cefiderocol	Injection	FDA recognizes M100 MIC standard and identifies disk diffusion STIC for *Stenotrophomonas maltophilia*. Rationale available at *https://www.fda.gov/drugs/development-resources/fda-rationale-recognition-decision-cefiderocol*.	Antibacterial	11/12/2024
Ceftaroline fosamil	Injection	FDA recognizes the M100 standard (MIC and disk diffusion) for *Staphylococcus aureus*. Rationale available at *https://www.fda.gov/drugs/development-resources/fda-rationale-recognition-decision-ceftaroline-fosamil-0*.	Antibacterial	6/25/2024
Ceftazidime	Injection	FDA concurs with CLSI to remove STIC (MIC) for *S. maltophilia.* Rationale available at *https://www.fda.gov/drugs/development-resources/rationale-fdas-position-ceftazidime-breakpoints-against-stenotrophomonas-maltophilia*.	Antibacterial	5/15/2024
Ceftobiprole medocaril sodium	Injection	FDA identified STIC for *S. aureus, Streptococcus pyogenes,* and Enterobacterales (MIC and disk diffusion), and for *Streptococcus pneumoniae, Haemophilus influenzae* and *H. parainfluenzae* (MIC).	Antibacterial	4/03/2024
Daptomycin	Injection	FDA recognizes M100 standard (MIC) for *Enterococcus faecium* and *Enterococcus* spp. other than *E. faecium*. Rationale available at *https://www.fda.gov/drugs/development-resources/fda-rationale-recognition-decision-daptomycin-0*.	Antibacterial	8/2/2024
Linezolid	Oral, Injection	FDA recognizes M100 (disk diffusion) standard for *S. aureus*	Antibacterial	5/28/2024
Piperacillin and Tazobactam	Injection	FDA has updated STIC (MIC and disk diffusion) for *P. aeruginosa*. FDA identified a susceptible-dose dependent breakpoint. FDA does not recognize M100 standard for susceptible, intermediate, and resistance breakpoints. Rationale available at *https://www.fda.gov/drugs/development-resources/fda-rationale-piperacillin-tazobactam-breakpoints-pseudomonas-aeruginosa*.	Antibacterial	3/22/2024
Pivmecillinam	Oral	FDA recognizes M100 standard (MIC and disk diffusion) for Enterobacterales.	Antibacterial	4/24/2024
Sulopenem etzadroxil and probenecid.	Oral	FDA identified STIC (MIC and disk diffusion) for Enterobacterales	Antibacterial	10/25/2024
Tedizolid phosphate	Oral, injection	FDA recognizes M100 (disk diffusion) standard for *S. aureus, Streptococcus* spp. beta-hemolytic group, and *Streptococcus* spp. viridans group.	Antibacterial	5/28/2024

[1] M100 standard in the table refers to CLSI Performance Standards for Antimicrobial Susceptibility Testing, 34th ed. CLSI supplement M100; 2024.

Dated: March 31, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–06048 Filed 4–8–25; 8:45 am]

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